STATEMENT OF EMERGENCY

907 KAR 1:479E, Durable Medical Equipment Covered Benefits and Supplies

(1) This emergency administrative regulation is being promulgated to revise medical data code sets used for reporting durable medical equipment, prosthetic, orthotic, and medical supply transactions. 45 C.F.R. 162.1002 requires the Department for Medicaid Services to use the medical data code sets maintained by the U.S. Department of Health and Human Services.

(2) This action must be taken on an emergency basis to comply with U.S. Department of Health and Human Services code changes effective July 1, 2004.

(3) This emergency administrative regulation shall be replaced by an ordinary administrative regulation filed with the Regulations Compiler.

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Ernie Fletcher
Governor

_____
James W. Holsinger, Jr., M.D., Secretary
Cabinet for Health and Family Services

CABINET FOR HEALTH AND FAMILY SERVICES

Department for Medicaid Services

Division of Hospital and Provider Operations

(Emergency Amendment)

907 KAR 1:479E. Durable medical equipment covered benefits and reimbursement.

RELATES TO: KRS 205.520, 42 C.F.R. 424.57, 440.230, 441 Subpart B, 45 C.F.R. 162.1002, 42 U.S.C. 1396d(r)

STATUTORY AUTHORITY: KRS 194A.030(2) [~~(3)~~], 194A.050(1), 205.520(3), 205.560, 42 U.S.C. 1396a, b, d, EO 2004 - 726

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health Services, Department for Medicaid Services, has responsibility to administer the Medicaid Program. Executive Order 2004 - 726, effective July 9, 2004, reorganized the Cabinet for Health Services and placed the Department for Medicaid Services and the Medicaid Program under the Cabinet for Health and Family Services. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law for the provision of medical assistance to Kentucky's indigent citizenry. This administrative regulation establishes the provisions relating to coverage and reimbursement requirements for durable medical equipment, medical supplies, prosthetics, and orthotics [~~for which payment shall be made by the Medicaid Program on behalf of both~~

~~the categorically needy and the medically needy~~].

Section 1. Definitions.

(1) "Certificate of medical necessity" or "CMN" means a form required by the Department for Medicaid Services to document medical necessity for durable medical equipment, medical supplies, prosthetics, and orthotics.

(2) "CMS" means the Centers for Medicare and Medicaid Services.

(3) "Covered benefit" or "covered service" means an item of durable medical equipment, a prosthetic, an orthotic, or a medical supply for which coverage is provided by the Kentucky Medicaid Program.

(4) "Customized" means that an item has been constructed, fitted, or altered to meet the unique medical needs of an individual Medicaid recipient and does not include the assemblage of modular components or the addition of various accessories that do not require unique construction, fitting, or alteration to individual specifications.

(5) "Date of service" means:

(a) The date the durable medical equipment, prosthetic, orthotic, or supply (DMEPOS) is provided to the recipient;

(b) For mail order DMEPOS, the later of the shipping date or the date the recipient was discharged home from an inpatient hospital stay or nursing facility;

(c) For DMEPOS delivered to a recipient’s home immediately subsequent to a hospital inpatient stay, the date of final discharge; or

(d) Up to two (2) days prior to discharge from a hospital or nursing facility if:

1. For purposes of fitting or training of the patient;

2. The item is ready for use in the recipient’s home; and

3. No billing is done prior to the date of the recipient's discharge from the facility.

(6) "Department" means the Department for Medicaid Services or its designated agent.

(7) "DMEPOS" means durable medical equipment, prosthetics, orthotics, and supplies.

(8) [~~"DMERC" means durable medical equipment regional carrier.~~

~~(9)~~] "Durable medical equipment" or "DME" means medical equipment which:

(a) Withstands repeated use;

(b) Is primarily and customarily used to serve a medical purpose;

(c) Is generally not useful to a person in the absence of an illness or injury; and

(d) Is appropriate for use in the home.

(9) [~~(10)~~] "HCPCS" means the Healthcare Common Procedure Coding System.

(10) [~~(11)~~] "Home" means a place where the recipient resides excluding:

(a) A nursing facility;

(b) A hospital;

(c) An intermediate care facility for the mentally retarded (ICF-MR); or

(d) An institution for individuals with a mental disease (IMD) as defined in 42 U.S.C. 1396d(i).

(11) [~~(12)~~] "Incidental" means that a medical procedure or service:

(a) Is performed at the same time as a more complex primary procedure or service; and

(b)1. Requires little additional resources; or

2. Is clinically integral to the performance of the primary procedure or service.

(12) [~~(13)~~] "Invoice price" means an itemized account of a manufacturer's actual charges that are billed to a supplier for goods or services provided by the manufacturer or distributor.

(13) [~~(14)~~] "Medicaid DME Program Fee Schedule" means a list located at http://chs.ky.gov/dms, containing the current Medicaid maximum allowable amount established by the department for a covered item of durable medical equipment, a prosthetic, an orthotic, or a medical supply.

(14) [~~(15)~~] "Medical supply" means an item that is:

(a) Consumable;

(b) Nonreusable;

(c) Disposable; and

(d) Primarily and customarily used to serve a medical purpose.

(15) [~~(16)~~] "Medically necessary" or "medical necessity" means that a covered benefit is determined to be needed in accordance with 907 KAR 3:130.

(16) [~~(17)~~] "Mutually exclusive" means that two (2) DMEPOS items:

(a) Are not reasonably provided in conjunction with one another during the same patient encounter on the same date of service;

(b) Represent duplicate or very similar items; or

(c) Represent medically inappropriate use of HCPCS codes.

(17) [~~(18)~~] "Nutritional supplement" means a liquid or powder administered enterally or orally that is specially formulated to supply complete diagnosis-appropriate nutrition, including kilocalories, protein, vitamins, and minerals.

(18) [~~(19)~~] "Orthotic" means a mechanical device or brace that is designed to

support or correct a defect or deformity or to improve the function of a movable part of the body.

(19) [~~(20)~~] "Prescriber" means a physician, podiatrist, optometrist, dentist, advanced registered nurse practitioner or physician's assistant who:

(a) Is acting within the legal scope of clinical practice under the licensing laws of the state in which the health care provider's medical practice is located;

(b) If an enrolled Kentucky Medicaid provider, is in compliance with all requirements of 907 KAR 1:671 and 907 KAR 1:672;

(c) Is in good standing with the appropriate licensure board and CMS; and

(d) Has the legal authority to write an order for a medically-necessary item of durable medical equipment, a medical supply, a prosthetic, or an orthotic for a recipient.

(20) [~~(21)~~] "Prior authorization" means approval which a supplier shall obtain from the department before being reimbursed.

(21) [~~(22)~~] "Prosthetic" means an item that replaces all or part of the function of a body part or organ.

(22) [~~(23)~~] "Reasonableness" means:

(a) The expense of the item does not exceed the therapeutic benefits which could ordinarily be derived from use of the item;

(b) The item is not substantially more costly than a medically-appropriate alternative; and

(c) The item does not serve the same purpose as an item already available to the recipient.

(23) [~~(24)~~] "Supplier" means a Medicare-certified provider of durable medical

equipment, medical supplies, prosthetics, or orthotics who is enrolled in the Kentucky Medicaid Program.

[~~(25) "Supplier manual" means the Medicare Region C DMERC DMEPOS Supplier Manual, 2002 edition.~~]

(24) [~~(26)~~] "Usual and customary charge" means the uniform amount that a supplier bills to the general public for a specific covered benefit.

Section 2. General Coverage.

(1) Coverage for an item of durable medical equipment, a medical supply, a prosthetic, or an orthotic shall:

(a) Be based on medical necessity and reasonableness;

(b) Require prior authorization in accordance with Section 7 of this administrative regulation;

(c) Be provided in compliance with 42 C.F.R. 440.230(c); and

(d) Be restricted to an item used primarily in the home.

(2) Unless otherwise established in this administrative regulation, Medicare criteria in effect on the date the durable medical equipment, prosthetic, orthotic or medical supply is provided [~~The Medicare Region C DMERC DMEPOS Supplier Manual, 2002 edition, accessible at: http://palmettogba.com/,~~] shall be used as a basis for the determination of coverage, but shall be subject to medical necessity override by the department to ensure compliance with 42 C.F.R. 440.230(c).

(3) Unless specifically exempted by the department, a DME item, medical supply, prosthetic, or orthotic shall require a CMN that shall be kept on file by the supplier for a period of five (5) years.

(4) An item for which a CMN is not required shall require a prescriber's written order.

(5) If Medicare is the primary payor for a recipient who is dually eligible for both Medicare and Medicaid, the supplier shall comply with Medicare's CMN requirement and a separate Medicaid CMN shall not be required.

(6) A required CMN shall be:

(a) The appropriate Medicare CMN in use at the time the item or service is prescribed; [~~or~~]

(b) A MAP-1000, Certificate of Medical Necessity; or [~~.~~]

(c) A MAP-1000B, Certificate of Medical Necessity, Metabolic Formulas and Food.

(7) A CMN shall contain:

(a) The recipient’s name and address;

(b) A complete description of the item or service ordered;

(c) The recipient’s diagnosis;

(d) The expected start date of the order;

(e) The length of the recipient’s need for the item;

(f) The medical necessity for the item;

(g) The prescriber’s name, address, telephone number and Unique Provider Identification Number (UPIN), if applicable; and

(h) The prescriber’s signature and date of signature.

(8) Except as specified in subsections (9) and (10) of this section, a prescriber shall examine a recipient within sixty (60) days prior to the initial order of a DME item,

medical supply, prosthetic, or orthotic.

(9) Except as specified in subsection (11) of this section, a prescriber shall not be required to examine a recipient prior to subsequent orders for the same DME item, medical supply, prosthetic, or orthotic unless there is a change in the order.

(10) A prescriber shall not be required to examine a recipient prior to the repair of a DME item, prosthetic, or orthotic.

(11) A change in supplier shall require a new CMN signed and dated by a prescriber who shall have seen the recipient within sixty (60) days prior to the order.

(12) A CMN shall be updated with each request for prior authorization.

(13) The department shall only purchase a new DME item.

(14) A new DME item that is placed with a recipient initially as a rental item shall be considered a new item by the department at the time of purchase.

(15) A used DME item that is placed with a recipient initially as a rental item shall be replaced by the supplier with a new item prior to purchase by the department.

(16) A supplier shall not bill Medicaid for a DME item, medical supply, prosthetic, or orthotic before the item is provided to the recipient.

Section 3. Purchase or Rental of Durable Medical Equipment.

(1) The following items shall be covered for purchase only:

(a) A cane;

(b) Crutches;

(c) A standard walker;

(d) A prone or supine stander;

(e) A vest airway clearance system, excluding the generator;

(f) A noninvasive electric osteogenesis stimulator; and

(g) Other items designated as purchase only in the Medicaid DME Program Fee Schedule.

(2) The following items shall be covered for rental only:

(a) An apnea monitor;

(b) A respiratory assist device having bivalve pressure capability with backup rate feature;

(c) A generator for use with a vest airway clearance system;

(d) A ventilator;

(e) A negative pressure wound therapy electric pump;

(f) An electric breast pump;

(g) The following oxygen systems:

1. Oxygen concentrator;

2. Stationary compressed gas oxygen;

3. Portable gaseous oxygen;

4. Portable liquid oxygen; or

5. Stationary liquid oxygen; and

(h) Other items designated as rental only in the Medicaid DME Program Fee Schedule.

(3) With the exception of items specified in subsections (1) and (2) of this section, durable medical equipment shall be covered through purchase or rental based upon anticipated duration of medical necessity.

Section 4. Special Coverage.

(1) An augmentative communication device or other electronic speech aid shall be covered for a recipient who is permanently unable to communicate through oral speech if:

(a) Medical necessity is established based on a review by the department of an evaluation and recommendation submitted by a speech-language pathologist; and

(b) Prior authorized by the department.

(2) A customized DME item that is uniquely constructed or custom fabricated to meet the medical needs of an individual recipient shall be covered only if a noncustomized medically appropriate equivalent is not commercially available.

(3) A physical therapy or occupational therapy evaluation shall be required for:

(a) A power wheelchair; or

(b) A wheelchair for a recipient who, due to size or medical condition, is unable to be reasonably accommodated by a standard wheelchair.

(4) Orthopedic shoes and attachments shall be covered if medically necessary for:

(a) A congenital defect or deformity;

(b) A deformity due to injury; or

(c) Use as a brace attachment.

(5) A therapeutic shoe or boot shall be covered if medically necessary to treat a nonhealing wound, ulcer, or lesion of the foot.

(6) An enteral or oral nutritional supplement shall be covered if:

(a) Prescribed by a licensed prescriber;

(b) Except for an amino acid modified preparation or a low-protein modified food

product specified in subsection (7) of this section, it is the total source of a recipient's daily intake of nutrients;

(c) Prior authorized; and

(d) Nutritional intake is documented on the CMN.

(7) An amino acid modified preparation or a low-protein modified food product shall be covered:

(a) If prescribed by a physician for the treatment of an inherited metabolic condition specified in KRS 205.560;

(b) If not covered through the Medicaid outpatient pharmacy program;

(c) Regardless of whether it is the sole source of nutrition; and

(d) If prior authorized.

(8) A DME item intended to be used for postdischarge rehabilitation in the home may be delivered to a hospitalized recipient within two (2) days prior to discharge home for the purpose of rehabilitative training.

(9) An electric breast pump shall be covered for the following:

(a) Medical separation of mother and infant;

(b) Inability of an infant to nurse normally due to a significant feeding problem; or

(c) An illness or injury that interferes with effective breast feeding.

Section 5. Coverage of Repairs and Replacement of Equipment.

(1) The department shall not be responsible for repair or replacement of a DME item, prosthetic, or orthotic if the repair or replacement is covered by a warranty.

(2) Reasonable repair to a purchased DME item, prosthetic, or orthotic shall be covered as follows:

(a) During a period of medical need;

(b) If necessary to make the item serviceable;

(c) If no warranty is in effect on the requested repair; and

(d) In accordance with Section 6(2) of this administrative regulation.

(3) Extensive maintenance to purchased equipment, as recommended by the manufacturer and performed by authorized technicians, shall be considered to be a repair.

(4) The replacement of a medically-necessary DME item, medical supply, prosthetic, or orthotic shall be covered for the following:

(a) Loss of the item;

(b) Irreparable damage or wear; or

(c) A change in a recipient's condition that requires a change in equipment.

(5) Suspected malicious damage, culpable neglect, or wrongful disposition of a DME item, medical supply, prosthetic, or orthotic shall be reported by the supplier to the department if the supplier is requesting prior authorization for replacement of the item.

Section 6. Limitations on Coverage.

(1) The following items shall be excluded from Medicaid coverage through the DME Program:

(a) An item covered for Medicaid payment through another Medicaid program;

(b) Equipment that is not primarily and customarily used for a medical purpose;

(c) Physical fitness equipment;

(d) Equipment used primarily for the convenience of the recipient or caregiver;

(e) A home modification;

(f) Routine maintenance of DME that includes:

1. Testing;

2. Cleaning;

3. Regulating; and

4. Assessing the recipient's equipment;

(g) Except as specified in Section 7(1)(k) of this administrative regulation, backup equipment; and

(h) An item determined not medically necessary by the department.

(2) An estimated repair shall not be covered if the repair cost equals or exceeds:

(a) The purchase price of a replacement item; or

(b) The total reimbursement amount for renting a replacement item of equipment for the estimated remaining period of medical need.

(3) Durable medical equipment, prosthetics, orthotics and medical supplies shall be included in the facility reimbursement for a recipient residing in a hospital, nursing facility, intermediate care facility for the mentally retarded, or an institution for individuals with a mental disease and shall not be covered through the durable medical equipment program.

Section 7. Prior Authorization Requirements and Process.

(1) Prior authorization shall be required for the following:

(a) An item or repair billed to the department at $150 or more;

(b) Rental of equipment;

(c) A therapeutic shoe or boot;

(d) Orthopedic shoes;

(e) An adjustment to a prosthetic or orthotic;

(f) An augmentative communication device;

(g) A customized DME item;

(h) A replacement DME item, prosthetic, or orthotic;

(i) A nutritional supplement;

(j) An amino acid modified preparation or a low-protein modified food product;

(k) Rental of a replacement wheelchair or ventilator during a repair to the recipient's primary equipment;

(l) A DMEPOS item denoted by a general or nonspecific HCPCS code;

(m) An item designated on the Medicaid DME Program Fee Schedule as requiring prior authorization;

(n) An item which exceeds the quantity limitation set in the Medicaid DME Program Fee Schedule; or

(o) An item designated by a HCPCS code not indicated on the Medicaid DME Program Fee Schedule that is determined by the department to be a covered benefit.

(2) If an item requires prior authorization, a supplier shall comply with the following:

(a) Submit all required documentation prior to the date of service; or

(b)1. Submit a written request within seven (7) business days to the department for prior authorization which shall include the prescriber's order; and

2. After receiving acknowledgement from the department that the prior authorization request is being processed, submit to the department a completed CMN and prior authorization form within thirty (30) business days.

(3) If an item requires an evaluation or recommendation by a specialist, the evaluation or recommendation shall be in writing and submitted with the CMN.

(4) The supplier shall not bill a recipient for a DME item, medical supply, prosthetic, or orthotic if the supplier has not completed the prior authorization process within the timeframe specified in subsection (2) of this section.

(5) If a supplier provides an item that requires prior authorization before the prior authorization is received, the supplier shall assume the financial risk that the prior authorization may not be subsequently approved.

(6) A supplier may initially obtain a faxed CMN from a prescriber to expedite the prior authorization process, but a signed, original CMN subsequently shall be required.

(7) A supplier shall request prior authorization by mailing or faxing the following information to the department:

(a) A completed prior authorization form MAP-9;

(b) A completed CMN; and

(c) If requested by the department, additional information required to establish medical necessity.

(8) The following additional information shall be required for prior authorization of a customized item:

(a) An estimate of the fitting time;

(b) An estimate of the fabrication time;

(c) A description of the materials used in customizing the item; and

(d) An itemized estimate of the cost of the item, including the cost of labor.

(9) The following additional information shall be required for prior authorization of

a repair to purchased equipment:

(a) A description of the nature of the repair;

(b) An itemization of the parts required for the repair;

(c) An itemization of the labor time involved in the repair; and

(d) A copy of the manufacturer's warranty indicating the purchase date or a written notice from the DME supplier stating that the requested repair is not covered by the warranty.

(10) An item shall be prior authorized based on the period of medical necessity but shall not exceed the maximum authorization period specified in the Medicaid DME Program Fee Schedule.

(11) A prior authorization period may be extended upon the provision of a new CMN indicating current medical necessity.

(12) Prior authorization by the department shall not be a guarantee of recipient eligibility. Eligibility verification shall be the responsibility of the supplier.

(13) Upon review and determination by the department that removing prior authorization shall be in the best interest of Medicaid recipients, the prior authorization requirement for a specific covered benefit shall be discontinued, at which time the covered benefit shall be available to all recipients without prior authorization.

(14) If it is determined by the department to be in the best interest of Medicaid recipients, the department shall have the authority to designate that an item of durable medical equipment suitable for use in the home [~~that~~] may be provided, if prior authorized, to a recipient temporarily residing in a hospital that does not bill patients, Medicaid, or other third-party payers for any health care services.

(15) For purposes of obtaining prior authorization, a signed invoice price quote from the manufacturer shall be acceptable documentation. If the invoice price differs from the manufacturer's invoice price quote, the supplier shall amend the prior authorization and shall maintain documentation of the quote and the invoice.

Section 8. Reimbursement for Covered Services.

(1) Except for an item specified in subsections (2) and (5) of this section, a new item that is purchased shall be reimbursed at the lesser of:

(a) The supplier's usual and customary charge for the item;

(b) The purchase price specified in the Medicaid DME Program Fee Schedule; or

(c) If indicated in the Medicaid DME Program Fee Schedule as manually priced:

1. Invoice price plus twenty (20) percent for an item not utilizing a billing code specified in subparagraph 2 or 3 of this paragraph;

2. The manufacturer’s suggested retail price minus fifteen (15) percent for HCPCS codes K0009 and K0014; or

3. The manufacturer’s suggested retail price minus twenty-two (22) percent for a customized component billed using HCPCS code K0108 or L8499.

(2) Pursuant to 45 C.F.R. 162.1002, the department shall recognize U.S. Department for Health and Human Services quarterly HCPCS code updates.

(a) If an item denoted by a changed or new HCPCS code has been determined by the department to be a covered service, the item shall be reimbursed at:

1. The Medicare maximum allowable rate for Kentucky less twenty (20) percent; or

2. If a Medicare maximum allowable rate is not available, the actual invoice price

plus twenty (20) percent.

(b) The department shall post HCPCS code change information on its web site accessible at http://chs.ky.gov/dms. The information may also be obtained by writing the Department for Medicaid Services at 275 East Main Street, Frankfort, Kentucky 40621.

[~~An item denoted by a HCPCS code not currently on the Medicaid DME Program Fee Schedule that has been determined by the department to be a covered service shall be manually priced using the actual invoice price plus twenty (20) percent~~.]

(3) In accordance with 907 KAR 1:604, if a copayment is required, reimbursement shall be reduced by the amount of the copayment.

(4) For a service covered under Medicare Part B, reimbursement shall be in accordance with 907 KAR 1:006.

(5) Reimbursement for the purchase of an item that is currently being rented shall be:

(a) For an item that has been rented for less than three (3) months, the purchase price specified in subsection (1) of this section minus the cumulative rental payment made to the supplier; or

(b) For an item that has been rented for three (3) months or more, 120 percent of the purchase price specified in subsection (1) of this section minus the cumulative rental payment made to the supplier.

(6) A rental item shall be reimbursed as follows, but reimbursement shall not exceed the supplier's usual and customary charge for the item:

(a) The rental price specified in the Medicaid DME Program Fee Schedule; or

(b) If indicated in the Medicaid DME Program Fee Schedule as manually priced:

1. Ten (10) percent of the purchase price per month for the monthly rental of an item; or

2. Two and one-half (2.5) percent of the purchase price per week for the weekly rental of an item that is needed for less than one (1) month.

(7) With the exception of an item specified in Section 3(2) of this administrative regulation, if reimbursement for a rental item has been made for a period of twelve (12) consecutive months, the item shall be considered to be purchased and shall become the property of the recipient.

(8) Labor costs for a repair shall be billed in quarter hour increments using the HCPCS codes for labor specified in the Medicaid DME Program Fee Schedule and shall be reimbursed the lessor of:

(a) The supplier's usual and customary charge; or

(b) The reimbursement rate specified in the Medicaid DME Program Fee Schedule.

(9) Reimbursement shall include instruction and training provided to the recipient by the supplier.

(10) The rental price of an item shall include rental of the item and the cost of:

(a) Shipping and handling;

(b) Delivery and pickup;

(c) Setup;

(d) Routine maintenance; and

(e) Essential medical supplies required for proper use of the equipment.

(11) The purchase price of a prosthetic or orthotic shall include:

(a) Acquisition cost and applicable design and construction;

(b) Required visits with a prosthetist or orthotist prior to receipt of the item;

(c) Proper fitting and adjustment of the item for a period of one (1) year;

(d) Required modification, if not a result of physical growth or excessive change in stump size, for a period of one (1) year; and

(e) A warranty covering defects in material and workmanship.

Section 9. Conditions for Provider Participation. A participating DME provider shall:

(1) Have an active Medicare DME provider number and adhere to all CMS supplier standards in accordance with 42 C.F.R. 424.57;

(2) Be enrolled in the Kentucky Medicaid Program in accordance with 907 KAR 1:671 and 907 KAR 1:672;

(3) Comply with the requirements [~~Abide by the rules and regulations~~] regarding the confidentiality of personal medical records pursuant to [~~as mandated by~~] 42 U.S.C. 1320d and [~~set forth in~~] 45 C.F.R. Parts 160 and 164; and

(4) Comply with the following:

(a) A supplier shall bill Medicaid rather than a recipient for a covered service;

(b) A supplier shall not bill a recipient for a service that is denied by the department on the basis that the service is incidental to, or mutually exclusive with, a covered service; and

(c) A supplier may bill a recipient for a service not covered by Medicaid if the provider so informed the recipient of noncoverage prior to providing the service.

Section 10. Appeal Rights.

(1) An appeal of a department decision regarding a Medicaid recipient based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:563.

(2) An appeal of a department decision regarding Medicaid eligibility of an individual shall be in accordance with 907 KAR 1:560.

(3) An appeal of a department decision regarding a Medicaid provider based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:671.

Section 11. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Form MAP-9, Prior Authorization Form, December 1995 edition", Department for Medicaid Services;

(b) "Form MAP-1000, Certificate of Medical Necessity, June 2003 edition", Department for Medicaid Services;

(c) "Form MAP-1000B, Certificate of Medical Necessity, Metabolic Formulas and Food, May 2004 edition", Department for Medicaid Services; and

["Medicare Region C DMERC DMEPOS Supplier Manual, Chapter 6, Chapter 8, and Chapters 18 through the Appendices of the 2002 edition"; and]

(d) "Medicaid DME Program Fee Schedule, July 1, 2004 [March 1, 2003] edition".

(2) This material may be inspected, copied or obtained, subject to applicable copyright law, at the Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. through 4:30 p.m.

Date	Russ Fendley, Commissioner Department for Medicaid Services
Date	Dr. Duane Kilty Undersecretary for Administration and Fiscal Affairs
Date	James. W. Holsinger, Jr., M.D., Secretary Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:479E
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Teresa Goodrich or Stuart Owen (502-564-6204)

(1) Provide a brief summary of:
  (a) What this administrative regulation does: This administrative regulation establishes coverage and reimbursement criteria for provision of durable medical equipment to the Medicaid eligible population.
  (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with federal and state laws requiring provision of medical services to Kentucky's indigent citizenry.
  (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation allows for the provision of medically necessary health services identified in KRS 205.560(1)(c).
  (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides the necessary criteria for the provision of medically necessary durable medical equipment services to Medicaid recipients.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
  (a) How the amendment will change this existing administrative regulation: This amendment revises medical data code sets used for reporting durable medical equipment, prosthetic, orthotic and medical supply transactions.
  (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to comply with 45 C.F.R. 162.1002(6) which specifies the medical data code sets the Department must use.
  (c) How the amendment conforms to the content of the authorizing statutes: This amendment revises medical data code sets used for reporting durable medical equipment, prosthetics, orthotics, and medical supply transactions to reflect updates issued by the U.S. Department of Health and Human Services for these transactions.
  (d) How the amendment will assist in the effective administration of the statutes: This amendment allows for the correct reporting of transactions involving items provided to Medicaid recipients through the Durable Medical Equipment (DME) Program.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: This administrative regulation affects the Department for Medicaid Services (DMS) and all DME suppliers (approximately 1,981).

(4) Provide an assessment of how the above group or groups will be impacted by either the implementation of this administrative regulation, if new, or by the change if it is an amendment: This amendment allows DMS to recognize the medical data code sets as amended by the U.S. Department of Health and Human Services which are used by DME suppliers to report DME transactions and receive correct reimbursement.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:
(a) Initially: Between $132,087 and $234,821 annually ($92,210 to $163,929 federal funds and $39,877 to $70,892 state funds)
(b) On a continuing basis: Same

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The next fiscal year budget may need to be adjusted to provide funds for implementing this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.

(9) Tiering: Is tiering applied? (Explain why tiering was or was not used)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The “equal protection” and “due process” clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FEDERAL MANDATE ANALYSIS COMPARISON

Reg. No. 907 KAR 1:479E Agency Contact: Teresa Goodrich or Stuart Owen (502-564-6204)

1. Federal statute or regulation constituting the federal mandate.

   45 C.F.R. 162.1002 requires the Department for Medicaid Services to use the medical data code sets maintained by the U.S. Department of Health and Human Services (HHS) for reporting durable medical equipment, prosthetic, orthotic and medical supply transactions. The U.S. Department of Health and Human Services periodically updates these code sets.

2. State compliance standards.

   This administrative regulation incorporates the most recent HHS medical data code set updates required for reporting durable medical equipment, prosthetic, orthotic and medical supply transactions.

3. Minimum or uniform standards contained in the federal mandate.

   The U.S. Department of Health and Human Services updated the medical data code sets required for reporting durable medical equipment, prosthetic, orthotic and medical supply transactions effective for July 1, 2004.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

   No. This administrative regulation does not set stricter requirements.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

   No additional standard or responsibilities are imposed.

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

907 KAR 1:479E, Durable Medical Equipment Covered Benefits and Reimbursement

Summary of Material Incorporated by Reference

The "MAP-1000B, Certificate of Medical Necessity, Metabolic Formulas and Food, May 2004 edition," used by agency staff and participating providers has been added. The form consists of 1 page.

The "Medicaid DME Fee Schedule, July 1, 2004 edition," replaces the "March 1, 2003 edition." This document is used by agency staff and participating providers and consists of 35 pages.

The "Medicare Region C DMERC DMEPOS Supplier Manual, 2002 edition," has been discontinued.

The "MAP-9, Form for Prior Authorization, December 1995 edition, " used by agency staff and participating providers remains unchanged. The form consists of 1 page.

The "MAP-1000, Certificate for Medical Necessity, June 2003 edition," used by agency staff and participating providers remains unchanged. The form consists of 2 pages.